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# Ethical Regulation of Medical Experiments on Humans

BY NICK AWERTSCHENKO '21

**Figure 1:** A doctor draws blood from one of the Tuskegee test subjects.

**Source:** Wikimedia Commons  
(Credit: National Archives)

Ethics should always be the primary concern regarding any research that involves human experimentation. Yet, in the Tuskegee Study (1), we see the consequences of 40 years of unregulated human experimentation violating any degree of ethical standards. This experiment was unethical from the start, as the potential knowledge that could have been gained from the experiment would not have been useful in treating patients in the future; all the experiment accomplished was risking the lives of and causing immense suffering to hundreds of patients with no possible medical benefit. Furthermore, the experiment completely lacked informed consent and instead, the Public Health Service or PHS (1) took advantage of the racial and socioeconomic status of the Macon County community to manipulate the uneducated population into agreeing to the study. Once word of the study spread throughout the scientific community, a few critics brought the moral and scientific flaws to light. However, since the study was regulated by the PHS, which was the same organization running the

study staffed by members who had been part of the study for years, these major problems were overlooked, and the study was allowed to continue for many decades. These major aspects of the Tuskegee study demonstrate the need for serious ethical regulation regarding any medical study regarding humans and provide insight on how this should be done in the future.

Opinion concerning the ethics of the Tuskegee experiment and human experimentation in general varies drastically, which is part of why universal ethical standards are difficult to define. Some experts defend the Tuskegee experiment from an ethical standpoint and justify withholding treatment of syphilis with the other types of medical care patients got instead and the risky nature of chemotherapy in the early years. Nurse Eunice Rivers, who was directly involved with bridging the gap between doctors and patients, justifies withholding treatment by claiming that the harmful effects of the early treatment were too severe, and that the patients received many other medical benefits to compensate for their lack of treatment.

She says, “I saw so many reactions with these medications[Neoarsphenamine and bismuth]... I didn’t feel good about neo and all this stuff ” (1). As James Jones, the author of *Bad Blood*, states, even if Nurse Rivers truly believed in this justification due to the potentially harmful side effects of early treatment, the argument falls apart when applied to withholding penicillin. In order to rationalize the later years of her involvement in the study, Rivers states, “They didn’t get treatment for syphilis, but they got so much else,” referring to the medical care they got from doctors regularly checking up on them and giving them free aspirin and “spring tonic” for their aches and pains (1). Dr. Heller, who was Dr. Vonderlehr’s successor as director of Division of Venereal Diseases, justifies continuing the study even with the advent of penicillin by stating “The longer the study, the better the ultimate information we would derive,” and looking back he does feel that the experiment was unethical but also believes it is not comparable to the Nuremberg trials (1).

On the other side of the spectrum, many experts believe that the Tuskegee study was immoral and have different notions of what makes a human experiment ethical. The first doctor to object to the ethics of the study was Dr. Irwin J. Schatz of Henry Ford Hospital who sent a letter to the author of an article on the study saying, “I am utterly astounded by the fact that physicians allow patients with a potentially fatal disease to remain untreated when effective therapy is available... I suggest that the[PHS doctors]... reevaluate their moral judgements...” (1). Schatz expresses his disapproval of withholding treatment from the men in the study due to moral concerns and was the first to do so by 1965, 23 years after the study begun. Another expert who opposes the study is Peter Buxtun, an investigator born to parents who fled Europe from the Nazis. Due to his background, Buxtun was able to draw the connection between the Nuremberg trials of the Nazis to the Tuskegee experiment and expressed to coworkers that “It [the Tuskegee study] didn’t sound like what a PHS institution should be doing” (1). Buxtun expressed “grave moral concerns about the experiment” and pointed out the lack of informed consent by saying, “they were nothing more than dupes and were being used as human substitutes for guinea pigs” (1). Many modern experts also have similar opinions on human studies in general, including Dr. Marcia Angell, executive editor of *The New England Journal of Medicine*, and Marc Lallemant, an investigator from Harvard, who openly express their opinions against using “dummy pills” for a more recent AIDS studies in third world countries (2). The Physicians Committee for Responsible Medicine (3) also

emphasizes the importance of taking morality seriously in any human experiment (3).

From the wide expert opinions on medical ethics, I would agree with Dr. Schatz, Peter Buxtun, and the Physicians Committee for Responsible Medicine that the morality of an experiment involving humans must be considered seriously. I feel that Dr. Schatz and Buxtun were completely correct for expressing their concerns to the PHS even at the risk of their careers, and that whistleblowers in the medical community should be commended for their actions. On the other hand, I completely disagree with Nurse Rivers’ and Dr. Heller’s opinions on the experiment, and I was disgusted by Heller’s absolute disregard for the wellbeing of the patients and Rivers’ delusional rationalization that she was helping the men by conducting the study. I believe that both Rivers and Heller should have their medical licenses and awards revoked due to their failure to practice medicine ethically under the Hippocratic Oath-- this would simultaneously serve as a form of justice as well as set an example for future practitioners of medicine. Regarding the placebo pills in third world countries, I believe that their usage is not nearly as unethical a practice as lying to patients with a fatal disease about treatment, but it should be required to test prototype drugs against the current standards instead of placebos. Since governments subsidize these experiments in the third world, it should be their responsibility to find the funding for these tests instead of putting the burden on the pharmaceutical companies.

In order to ameliorate the condition of human medical research, I think that human experimentation needs to be heavily regulated to ensure that it is kept within the bounds of current ethical standards. I would define these standards to include a need for informed and voluntary consent of the subjects, as well as a clear potential benefit that could improve humanity significantly enough to justify the potential risks on the subjects. In order to create and enforce these regulations, the government may need to create an organization purely to pass and enforce laws regarding this issue. This organization should not engage in research itself as this would make proper enforcement of ethical standards impossible, which is exactly what happened with the PHS’s attempt to assess itself during the Tuskegee study. The organization should be publicly open about its actions in order to allow for the general public to help determine what is ethical. This should also be brought up to an international level so that ethical standards can be kept consistent across the globe.

The first step in attaining ethical standards in medical experiments on humans is to define

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**Figure 2:** Subjects talking with study coordinator, Nurse Eunice Rivers c. 1970.

**Source:** Wikimedia Commons  
[Credit: Center for Disease Control and Prevention]

those standards. From analyzing the flaws in the Tuskegee study as well as the testimonials of experts and non-experts, I have narrowed down a few crucial factors that determine the morality of a human experiment. The first is that in order for an experiment to be ethical, its risks must be justifiable by a potential benefit for humanity greater than the risks it imposes on the subjects. This should be common sense since it is never ethical to harm other people for no reason; however, the doctors conducting the Tuskegee study seemed to have missed this important checkpoint when assessing their experiment. In the case of the Tuskegee study, the scientific knowledge that could have been gained was only for curiosity, as there was no intention of coming up with an improved cure from the study. Jones' book puts it well with the 12th chapter title: “Nothing Learned Will Prevent, Find, or Cure a Single Case.” This first qualification for an ethical study is also supported by my personal communication with peers, who also brought up the point that humans should only be tested if it is for the greater good of society. Moreover, the Physicians Committee for Responsible Medicine also agrees that any unnecessary experimentation should be avoided, including testing for patents on new drugs that are “essentially a copy of an existing drug” (3).

A second requirement for meeting ethical

standards should be the voluntary and informed consent of participants in the study. This means that subjects of the experiment should not be pressured to join or taken advantage of due to their racial, socioeconomic, or any other type of status. Instead, researchers should seek volunteers who understand the risks of the study and agree to partake in the study. This also should be common sense since it is never ethical to forcefully impose health risks on another person without their agreement to it. Like the first requirement, the need for informed consent was also not met during the Tuskegee study, as the uneducated, poor, and historically neglected black population of Macon County was an easy target for deceit. Similarly, the National Academy of Sciences revealed in 1993 that the U.S. military had been conducting chemical weapons tests from 1944 to 1977 on thousands of American GIs and radiation tests on over two hundred thousand civilians all without their informed consent (3). These practices are not morally acceptable and call for the need of informed consent. These two principles of ethics must be taken into account whenever conducting human experiments and should be incorporated into legal policies governing medical research.

Once regulatory policy is built based on these requirements, a government organization needs to be created to enforce these regulations



and keep them up to date with current medical practices. The government organization should not conduct any research itself and should remain completely unaffiliated with any organization or company that does conduct medical research. The reason for this is to ensure that the medical research community can have an unbiased governing body completely devoted to maintaining the ethics of any experiments being conducted. History and common sense demonstrate that leaving private companies or government organizations to regulate their own research will not be effective due to the immense conflict of interest that self regulation creates. Looking back at the Tuskegee Study, the PHS attempted to inspect itself by creating an ad hoc counsel of its own members to determine the flaws of their own study. Due to the biases of the members and the potential career consequences speaking out would entail, no significant progress was made on seeing the ethical problems. In modern medical research, experiments on humans are required to follow the Common Rule, which was made in 1991 and “defined human participant research, specified the role and scope of informed consent, and required research oversight and compliance through institutional review boards (IRBs) at participating research entities.” In addition, many government agencies were formed to help regulate human research including the Office for Human Research Protections (OHRP). These steps that the government has taken in response to Tuskegee are good progress; however, there is still much room for improvement. For example, a current problem with the policy is that it has become out of date due to changes in medical practices, so a new version of the law has been passed and will take effect starting in 2018 (4).

The final step in ensuring that human medical research is as ethical as possible is expanding the scope of regulation to the public. I believe that it is essential for the public to be involved as educated observers in order to make sure that both private companies as well as government regulatory bodies are following ethical protocol. In this way, the public serves as an additional check on the government organizations. In order to ensure that the public gets involved, the government agencies must have a high level of transparency and must work to spread awareness of important ethical issues in human research. One way this can be done is by using correct terms when describing an experiment. In a linguistics article, George Annas points out that “Even a cursory examination of modern human experimentation demonstrates the pervasiveness of three doublespeak concepts: experimentation is treatment, researchers are physicians, and subjects are patients”(Elliot). This demonstrates the power of the language

used to describe human experiments; in modern medical experiments, researchers market their human experiment as a study to make it seem harmless, as the term “study” has a much less serious connotation than “human experiment” does. In this way, researchers are able to deceive many people into participating since they overlook the risks once they have perceived it as a harmless study.

Possible objections to the need for strong regulation of an ethical standard in human medical research include its questionable practicality and whether regulation will be able to keep up with changes in medical practices. The first objection is reasonable since government agencies are not infallible and do have a chance of falling to corruption and bribery by large pharmaceutical companies. In order to mitigate this risk, these regulatory government agencies should be very open to the public about their actions in order to allow the general population to act as a check and balance. Another objection stems from the possibility of companies outsourcing human experimentation to overseas outside of U.S. regulatory bodies’ jurisdiction. For this reason, I think it is important to add informed consent on human experimentation to the list of basic human rights that the United Nations protects in order to have international compliance with ethical standards. Finally, there is the issue of changes in medical practices due to accelerating globalization and technological growth outpacing regulation. This concern is valid and is a major problem across all types of government regulation. The best solution to this would be to adhere to the general principles of ethics at all times so that even when specific regulation laws become obsolete due to new procedures and technology, experimentation is still bound by the basic foundation of ethics.

The importance of regulation on human medical experiments is incontrovertible due to the story that the history tells us of the consequences of unregulated or under-regulated human experimentation. If adequate regulation is not implemented, repeats of Tuskegee, chemical weapons tests, radiation tests, AIDS placebo tests, and many more of the type are certain to occur. Therefore, it is important to set up the rules in such a way that pharmaceutical companies are incentivized to conduct only ethical research with the informed consent of the subjects and the potential benefits to humanity in mind. In order to implement these rules, a new government organization should be created with the purpose of keeping experiments in check legally. This organization would differ from current organizations since it would be connected to the legal department and be overseen by the attorney general. This would ensure that this regulatory organization will have

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legal jurisdiction to enforce federal regulations at any time during the study. This is opposed to the current Institutional Review Boards that are in place and only determine if a study can begin according to the guidelines set by the institution. A federal legal organization could also conduct random reviews mid-experiment for a certain percent of human experiments conducted in the country. The reason this is an important improvement from IRBs is because oftentimes a study will change its course as it goes on, escaping the regulation of IRBs, which only check the study at its inception. A recent example of this is the Polyheme testing, which was a test for a substitute for blood transfusions during emergency situations. The study started out by following informed consent standards; however, this changed as the study went on. An article on the ethics of this study states, “Trialing the product in an emergency medical services setting, though, would require using waivers of consent under the 1996 FDA rule”(5). In this situation, Polyheme changed the course of their study and in the process, lost the informed consent that was originally part of the study and cost the lives of many patients who were unwillingly subject to the study. While the study was eventually stopped, it took a long time to end, and during that time, many casualties occurred. To fix this, a new government organization that performs random reviews on ongoing studies should be created. This solution would create incentives for companies that sponsor research to stay on track with the approved guidelines of the study as well as terminate any studies that start being unethical early in order to minimize casualties.

From the chart below (Figure 3), it is evident that Polyheme resulted in more deaths than the control during the two days for which data was

provided. Many of these unnecessary deaths may be avoided if a government organization conducting random reviews on ongoing research could cut the study short. **D**

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**Figure 3:** Death rates for Polyheme and control subjects.

**Source:** McKenna, M (2006). Polyheme and the Ethics of Informed Consent. *Annals of Emergency Medicine*, 48 (5), Nov. 2006, pp. 563–567.

